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EXAMINER	
BHAT, NARAYAN KAMESHWAR	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,176	OKAMURA ET AL.	
	Examiner	Art Unit	
	NARAYAN K. BHAT	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,19-21,31 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17, 19-21 and 31-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

1. This action is in response to the papers filed on September 03, 2009. Applicants have amended claim 17 and cancelled claim 18. Applicant's arguments filed on September 03, 2009 have been fully considered and are not persuasive as addressed following rejections. Accordingly, **THIS ACTION IS MADE FINAL.**

Claim Status

2. Claim 17 is amended and claim 18 is cancelled. Claim amendments have been reviewed and entered. Applicant's arguments filed on September 03, 2009 have been fully considered and addressed following rejections. Previous rejections under 35 USC 102 or 103 (a) not reiterated below are withdrawn in view of claim amendments.

3. Claims 17, 19-21 and 31-32 are pending in this application and are under prosecution.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were

made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 17, 19-20 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwaki et al by Iwaki et al (USPN 6,858,392, effective filing date Dec. 13, 2000) in view of Mao et al (USPGPUB 20030124332, effective filing date Aug. 28, 2001).

Claim 17 recites following structural components: a) a substrate, b) positively charged electrostatic layer on the substrate, c) a chemically modifying layer containing a carboxyl group on the electrostatic layer and d) a nucleic acid molecule covalently bonded to the chemically modifying layer. Iwaki et al teaches structural components 'a' to 'd' except for the carboxyl group on the chemically modifying layer as described below.

Regarding structural component 'a', Iwaki et al teaches a substrate 1 (Fig. 1, column 4, line 35).

Regarding structural component 'b', Iwaki et al teaches poly-L-lysine layer X (i.e., an electrostatic layer) comprising a positively charged amino group compound on the substrate (Fig. 1, column 5, lines 40-44).

Regarding structural component 'c', Iwaki et al teaches an E-G layer on the electrostatic layer, i.e., chemically modifying layer (Fig. 1, panel two from the top,

column 4, lines 35-41) making it possible to introduce a sulfonic function group capable of covalently binding to a nucleic acid molecule (column 4, lines 1-3 and 45-50). Iwaki et al do not teach chemically modifying layer containing a carboxyl group.

Regarding structural component 'd', Iwaki et al teaches a nucleic acid molecule bonded covalently to the chemically modifying layer (Fig. 1, panel 3 from the top, column 4, lines 1-3 and 45-50).

Regarding claim 19, Iwaki et al teaches that electrostatic layer comprising poly L-lysine has non-covalent amino group distal to the substrate (Fig. 1, column 5, line 44). Therefore, electrostatic layer include an amino group containing compound that does not covalently bound to the substrate.

Regarding claim 20, Iwaki et al teaches a solid support wherein an electrostatic layer comprises an amino group-containing polymer, silane (Fig. 1, column 5, lines 50-53) and further teaches that the polymer binds covalently to the substrate and also has free amino group to introduce functional group (column 5, lines 50-56), which encompasses a compound containing an amino group at the terminus to which the substrate does not bind.

Regarding claim 31, Iwaki et al teaches that nucleic acid molecule is immobilized as a spot (Fig. 4, column 4, lines 1-3 and 45-50).

As described above, Iwaki et al do not teach chemically modifying layer containing a carboxyl group. However, chemically modifying layer containing a carboxyl group was known in the art at the time of the claimed invention was made as taught by Mao et al.

Mao et al teaches a solid support comprising a substrate and a first layer (i.e., an electrostatic layer) comprising a positively charged amino group compound on the substrate (Fig. 1F, paragraph 0046). Mao et al teaches a second layer (i.e., chemically modifying layer) on the electrostatic layer comprising polyacrylic acid containing carboxyl functional groups (paragraphs 0046, and 0049) capable of covalently binding to a nucleic acid molecule (paragraphs, 0045, 0049 and 0105).

Mao et al also teaches that the solid support comprising multilayer coated materials have high density of functional groups, limited leaching and strong and specific binding ability to a variety of agents and used for a variety of applications (paragraph 0017).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the chemically modifying layer of Iwaki et al with layer comprising carboxyl functional group of Mao et al with a reasonable expectation of success.

An artisan would be motivated to modify the chemically modifying layer of Iwaki et al with the expected benefit of having a chemically modifying layer with high density of carboxyl functional groups with limited leaching and strong and specific binding ability to a variety of agents for a variety of applications as taught by Mao et al (paragraph 0017).

7. Claims 17, 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwaki et al (USPN 6,858,392, effective filing date Dec. 13, 2000) in view of Mao et

al (USPGPUB 20030124332, effective filing date Aug. 28, 2001) as applied to claim 17 as above and further in view of Woo et al (USPN 5,929,194 issued July 27, 1999).

Claim 21 is dependent from claim 19, which is dependent from claim 17. Teachings of Iwaki et al and Mao et al regarding claims 17 and 19 are described above in section 6.

Regarding claim 21, Iwaki et al teaches a variety of amino group containing compounds including polylysine and silane (column 5, lines 44 and 50-51). Iwaki et al in view of Mao et al do not teach amino group containing compound polyarylamine. However, amino group containing compound polyarylamine was known in the art at the time of the claimed invention was made as taught by Woo et al, who teaches polyarylamine compound for coating substrates and forming films on the substrate carrying positive charges (column 4, lines 8-10). Woo et al further teaches that the coating with polyarylamine makes the support solvent resistant and useful for fluorescent coating and as a protective coating for electronic devices (column 4, lines 10-11, column 14, lines 13-17).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the substrate of Iwaki et al and Mao et al with the polyarylamine coated substrate of Woo et al with a reasonable expectation of success with the expected benefit of generating fluorescent coatings, protective coatings for electronic devices as taught by Woo et al (column 14, lines 13-17).

8. Claims 17 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwaki et al (USPN 6,858,392, effective filing date Dec. 13, 2000) in view of Mao et al (USPGPUB 20030124332, effective filing date Aug. 28, 2001) as applied to claim 17 as above and further in view of Bertrand et al (Macromol. Rapid Commun., 2000, 21, 319-348).

Claim 32 is dependent from claim 17. Teachings of Iwaki et al and Mao et al regarding claim 17 are described above section 6.

Regarding claim 32, Iwaki et al teaches an electrostatic layer (Fig. 1, Top panel). Iwaki et al in view of Mao et al do not teach the thickness of the electrostatic layer is 1 nm to 500 micron. However, the thickness of the electrostatic layer was known in the art at the time of the claimed invention was made as taught by Bertrand et al.

Bertrand et al teaches a solid support comprising an electrostatic layer, wherein the thickness of the layer is from few angstroms to micrometer (Fig. 1 and pg. 319, column 2, lines 4-5), which is in the claimed range of 1 nm to 500 micron. Bertand et al further teaches that the electrostatic layer is very stable against mechanical stress or solvents (pg. 325, column 1, lines 1-3).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the thickness of electrostatic layer of Iwaki et al with the electrostatic layer of micrometer thickness of Bertrand et al with a reasonable expectation of success with the expected benefit of having electrostatic layer, which is very stable against mechanical stress or solvents as taught by Bertrand et al (pg. 325, column 1, lines 1-3).

9. Claims 17, 19-20 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mao et al (USPGPUB 20030124332, effective filing date Aug. 28, 2001) in view of Mirus et al (WO 01/02538 published Jan. 11, 2001).

Claim 17 recites following structural components: a) a substrate, b) positively charged electrostatic layer on the substrate, c) a chemically modifying layer containing a carboxyl group on the electrostatic layer, d) a nucleic acid molecule covalently bonded to the chemically modifying layer. Mao et al teaches structural components 'a' to 'd' except for explicitly teaching covalent linking of nucleic acids.

Regarding structural component 'a', Mao et al teaches a substrate (Fig. 1F and paragraph 0046, line 9).

Regarding structural component 'b', Mao et al teaches a first layer (i.e., an electrostatic layer) comprising a positively charged amino group compound on the substrate (Fig. 1F, paragraphs 0046 and 0069).

Regarding structural component 'c', Mao et al teaches a second layer)i.e., chemically modifying layer) on the electrostatic layer (Fig. 1F, paragraph 0046). Mao et al further teaches that second layer comprises polyacrylic acid (paragraph 0069) containing carboxyl functional groups (paragraph 0105) capable of covalently binding to a nucleic acid molecule (paragraph 0045). While, Mao et al suggests bound nucleic acid, the reference does not specifically teach a nucleic acid molecule bonded covalently to the chemically modifying layer.

Regarding claim 19, Mao et al teaches a solid support wherein the first layer (i.e., an electrostatic layer) comprises an amino group-containing polymer, polylysine

(paragraph 0069) and further teaches that the polymer binds to the substrate by an electrostatic interactions (paragraph 0018), thus teaching an amino group containing compound that does not covalently bind to the substrate.

Regarding claim 20, Mao et al teaches that the first layer (i.e., an electrostatic layer) comprises an amino group-containing compound (paragraph 0069) and further teaches that the polymer binds to the substrate through covalent bonds (paragraph 0018). Mao et al also teaches that the first layer comprising of amino group forms an amide bond with the carboxyl group of the polymer of the second layer (paragraph 0099) thus teaching a compound containing an amino group at the terminus to which the substrate does not bind.

Regarding claim 31, Mao et al clearly suggest nucleic acid molecules are immobilized on the solid support (paragraph 0045) but do not teach about immobilizing as a spot.

As described above, Mao et al suggests bound nucleic acid, however, the reference does not specifically teach a nucleic acid molecule bonded covalently to the chemically modifying layer.

However, a nucleic acid molecule bonded covalently to the chemically modifying layer and immobilizing nucleic acid as a spot were known in the art at the time of the claimed invention was made as taught by Mirus et al.

Mirus et al teaches a solid support for nucleic acid immobilization comprising a substrate (pg. 4, line 30) and further teaches a chemically modifying layer, polyanion layer making it possible to introduce a carboxyl functional group (pg. 5, lines 3-9). Mirus

et al further teaches that a nucleic acid molecule bonded covalently to the chemically modifying layer (pg. 3, lines 7-10).

Mirus et al also teaches that the nucleic acid molecule is immobilized as a spot (pg. 10, lines 3 and 29-30).

Mao et al suggests the covalent binding of nucleic acids to the functional groups on the surface of the chemically modified layer comprising poly acrylic acids (pg. 8, lines 23-27). Mirus et al teaches the covalent bonding of nucleic acids to the carboxyl groups on the chemically modified layer and immobilizing nucleic acids as a spot on the substrate, thus meeting the limitation of structural components recited in claims 17 and 31.

Mirus et al also teaches that covalent binding of nucleic acids increases the concentration of the nucleic acids irrespective of their size on the support, forming a three dimensional lattice and increases the sensitivity of target detection (Tables 1-4, pg. 15, lines 9-13).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the nucleic acid immobilization to the substrate of Mao et al with covalent attachment of nucleic acid with a carboxyl functional group on the substrate of Mirus et al with a reasonable expectation of success with the expected benefit of covalent binding of nucleic acids increasing the concentration of the nucleic acids irrespective of their size on the support, forming a three dimensional lattice and increasing the sensitivity of target detection as taught by Mirus et al (Tables 1-4, pg. 15, lines 9-13).

10. Claims 17, 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mao et al (USPGPUB 2003/0124332, effective filing date Aug. 28, 2001) in view of Mirus et al (WO 01/02538 published Jan. 11, 2001) as applied to claims 17 and 19 as above and further in view of Woo et al (USPN 5,929,194 issued July 27, 1999).

Teachings of Mao et al and Mirus et al regarding claims 17 and 19 are described above in section 9.

Regarding claim 21, Mao et al teaches a variety of amino group containing compounds including polylysine (paragraph 0019). Mao et al and Mirus et al do not teach about the amino group containing compound polyarylamine. However, amino group containing compound polyarylamine was known in the art before the claimed invention was made as taught by Woo et al, who teaches polyarylamine for coating substrates and forming films on the substrate carrying positive charges (column 4, lines 8-10). Woo et al further teaches that coatings with polyarylamine makes the support solvent resistant and useful as a fluorescent coating, as a protective coating for electronic devices (column 4, lines 10-11, column 14, lines 13-17).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the substrate of Mao et and Mirus et al with the polyarylamine coated substrate of Woo et al with a reasonable expectation of success with the expected benefit of generating fluorescent and protective coatings for electronic devices as taught by Woo et al (column 14, lines 13-17).

11. Claims 17 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mao et al (USPGPUB 2003/0124332, effective filing date Aug. 28, 2001) in view of Mirus et al (WO 01/02538 published Jan. 11, 2001) as applied to claim 17 as above and further in view of Bertrand et al (Macromol. Rapid Commun., 2000, 21, 319-348).

Teachings of Mao et al and Mirus et al regarding claim 17 are described above in section 17.

Regarding claim 32, Mao et al teaches that that electrostatic layer comprises of varying thickness (paragraph 0102). Mao et al and Mirus et al do not teach about the thickness of the electrostatic layer is 1 nm to 500 micron. However, the thickness of the electrostatic layer was known in the art at the time of the claimed invention was made as taught by Bertrand et al.

Bertrand et al teaches a solid support comprising a electrostatic layer, wherein the thickness of the of the layer is from few angstroms to micrometer (Fig. 1 and pg. 319, column 2, lines 4-5) and further teaches that the electrostatic layer is very stable against mechanical stress or solvents (pg. 325, column 1, lines 1-3).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the substrate of Mao et and Mirus et al with the electrostatic layer of micrometer thickness of Bertrand et al with a reasonable expectation of success with the expected benefit of having electrostatic layer, which is very stable against mechanical stress or solvents (pg. 325, column 1, lines 1-3).

Response to remarks from Applicants

Claim rejections under 35 U.S.C. § 102

12. Applicant's arguments filed September 3, 2009 with respect to claims 17, 19, 31 and 32 as being anticipated by Jordan et al have been fully considered (Remarks, pgs. 4 and 5). These arguments are moot in view of claim amendments and withdrawn rejections.

Applicant's arguments with respect to claims 17, 19, 20 and 31 as being anticipated by Iwaki et al have been fully considered (Remarks, pgs. 4 and 5). These arguments are moot in view of claim amendments, withdrawn rejections and new grounds of rejections as set forth in this office action. Applicants arguments regarding teachings of Iwaki et al as it pertains to the rejections made in this office action are addressed below.

Claim rejections under 35 U.S.C. § 103(a)

13. Applicant's arguments filed September 3, 2009 with respect to claims 17 and 20 as being unpatentable over Jordan in view of Iwaki have been fully considered (Remarks, pg. 6) but are moot in view of amended claims and withdrawn rejections.

Applicant's arguments with respect to claims 17, 19 and 21 as being unpatentable over Jordan in view of Woo have been fully considered (Remarks, pgs. 6 and 7) but are moot in view of amended claims and withdrawn rejections.

Applicant's arguments with respect to claim 17 as being unpatentable over Iwaki in view of Mao are directed to Mao disclosing carboxylic groups on a porous substrate

and materials are used for making films and why one would incorporate layer of Mao into the detection device of Iwaki (Remarks, pg. 7). These arguments have been fully considered but are not persuasive because as described above in section 6, Iwaki teaches recited structural components of a solid support except for the chemically modifying layer containing carboxyl functional group, which is taught by Mao.

Mao further provides teachings, suggestions and motivations to modify the solid support of Iwaki for having a solid support with limited leaching and strong and specific binding ability to a variety of agents to the solid support (paragraph 0017). Furthermore, Applicants have not provided any factual evidence that layer containing carboxyl functional group of Mao, would not work in the solid support of Iwaki. Iwaki and Mao teaches claimed structural components of the claimed solid support, thereby meeting the limitation of the claim (MPEP 2114).

Applicants further argue that Mao discloses carboxylic groups can be introduced in porous support for membranes, films, conjugate pads but argues that it is not understood why one would incorporate layer of Mao into the detection device of Iwaki (Remarks, pg. 7, and last paragraph). This argument is not persuasive because as described above, Mao teaches chemically modifying layer containing carboxyl functional group provides strong and specific binding of nucleic acids (paragraphs 0017 and 0024). Furthermore, Applicants have not traversed the teachings, suggestions and motivations of Mao as presented in the office action. Therefore arguments are not persuasive.

Applicants further argue that polyaryl amine of Woo is crosslinkable and further asserts that cross linked polyaryl amine of Woo would not have amino group that binds (Remarks, pg. 8, paragraph 3). This argument is similar to the one made for the carboxyl functional group and are not persuasive for the same reasons as described above.

Applicants remaining arguments of counsel regarding teachings of Iwaki, Mao and Bertrand (Remarks, pg. 8 and last paragraph), Mao in view Mirus (Remarks, pg. 9, paragraph 4), Mao, Mirus and Woo (Remarks, pg. 9 and last paragraph), and Mao, Mirus and Bertrand (Remarks, pg. 10 and last paragraph) are similar to the one made for other combination references as described above. These arguments are not persuasive for the same reasons as described above.

Conclusion

14. No claims are allowed.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571)-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Narayan K. Bhat

Examiner, Art Unit 1634

/BJ Forman/

Primary Examiner, Art Unit 1634